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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,107	08/09/2001	Toufic Renno	PF91PCT SEQ/dln	5104

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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,107	RENNO ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 25-40 are drafted as non-statutory "use" claims under 35 U.S.C. 101 and as such are improper process claims (MPEP 2173.05(q)). For compact prosecution, the claims have been interpreted as set for the below. In response to this restriction requirement, Applicant is required to amend the claims as proper process claims in order to have compact prosecution in the present application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 25 is an enterobacterium OmpA protein associated with SEQ ID No. 3 that generates a cytotoxic T response to melanoma cells. The claim lacks inventive step over Rauly et al (Res. Immun. 149:99, 1/1998, IDS filed 08/09/2001) in view of Valmori et al (J. Immun. 160:1750-1758, 2/1998, IDS filed 08/09/2001). Rauly et al teach an enterobacterium OmpA protein that generates a cytotoxic T response demonstrating that OmpA can be used as a carrier protein for stimulating the immune system. Rauly et al does not teach that SEQ ID No. 3 generates a cytotoxic T response to melanoma cells. Valmori et al teach that SEQ ID No. 3 generates a cytotoxic T response to melanoma cells, albeit a

weak one. Therefore, claim 25 lacks inventive step, because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use OmpA as a carrier protein associated with SEQ ID No. 3 to generate a cytotoxic T response to melanoma cells and, more specifically, an increased cytotoxic T response when compared to SEQ ID No. 3 alone. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 25-36 and 39-40, drawn to a method of using the polypeptides of OmpA and SEQ ID No. 3 in a pharmaceutical composition to generate a cytotoxic T response against melanoma cells.

Group II, claims 37-38, drawn to method of using the polynucleotides of OmpA and SEQ ID No. 3 in a pharmaceutical composition to generate a cytotoxic T response against melanoma cells.

Group III, claims 41-48, drawn to a pharmaceutical composition comprising the polypeptides of OmpA and SEQ ID No. 3.

Group IV, claim 43, drawn to a pharmaceutical composition comprising polynucleotides of OmpA and SEQ ID No. 3.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above,

Claim 25 lacks inventive step over Rauly et al in view of Valmori et al. Therefore, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 25 is not special.

The inventions are independent or distinct, each from the other because:

The methods of Inventions of Group I and II differ in that the reagents used are structurally and chemically distinct and are not required one for the other. Group I recites using polypeptides in a pharmaceutical composition, while Group II recites using polynucleotides in a pharmaceutical composition. The examination of all groups would require different searches of U.S. Patents and the scientific literature and would require the consideration of different patentability issues. Thus, Inventions I and II are separate and distinct in the reagents used and are patentably distinct.

Inventions of Groups III and IV represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. Group III recites using polypeptides that are structurally and functionally distinct from the polynucleotides of Group IV. Additionally, the polynucleotides of Group IV are made by nucleic acid synthesis, while the polypeptides of Group III are made by translation of mRNA. Furthermore, the polynucleotide can be used for hybridization screening and the polypeptide can be used to raise antibodies, for example. The examination of all groups would require different searches of U.S. Patents and the scientific literature and would require the consideration of different patentability issues. Thus the inventions of Group III and IV are patentably distinct.

Inventions of Group I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides in the composition of Group III could be used to raise antibodies, which differs in the method objective, method steps, parameters, reagents used and endpoint from the therapeutic method of Group I and is therefore distinct.

Inventions of Group II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides in the composition of Group IV could be used to produce the polypeptides they encode, which differs in the method objective, method steps, parameters, reagents used and endpoint from the therapeutic method of Group II and is therefore distinct.

The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-IV are patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

David Blanchard, AU1643